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APPENDIX A

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BOARD OF APPEALS

SEP 11 1974

U.S. PATENT OFFICE

Appeal No. 151-56

IN THE UNITED STATES PATENT OFFICE

BEFORE THE BOARD OF APPEALS

Ex parte Christian J. Jansen, Jr.

Application for Patent filed July 22, 1970, Serial No. 57,302. Hematinic-Vitamin Preparation.

Woodard, Weikart, Emhardt and Naughton for appellant.

Before Magil and Schneider, Examiners-in-Chief, and Milestone, Acting Examiner-in-Chief.

Magil, Examiner-in-Chief.

This is an appeal from the final rejection of claims 1 through 11, all the claims now in the case.

Claims 1 and 11 are illustrative of the appealed claims and read as follows:

1. In an improved oral multifactor hematinic vitamin preparation which contains vitamin B_{12} and folic acid, the improvement which comprises having at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid, in an approximate one to one ratio.

11. A method of treating and preventing anemia in humans which comprises administering a daily oral dosage of a vitamin preparation containing at least .5 mg. of vitamin B_{12} and at least .5 mg. of folic acid, whereby anemia can safely be treated orally without determining whether it is caused by folic acid deficiency or by vitamin B_{12} deficiency.

Claims 2 through 10 are all composition claims. Claim 2, dependent on claim 1, places an upper limit of 1 milligram on each of the components. Claims 3 through 7 are specific formulations including other vitamins and, in the case of claims 5 and 7, elemental iron. Claim 8 specifies the same two components as claim 1 but does not require a "one to one ratio." Claims 9 and 10 require 0.5 mg. of each of the two ingredients, with the last of these claims adding elemental iron. Classified somewhat differently, claims 1, 2, and 8 include as little as 0.1 mg. of folic acid and 0.1 mg. vitamin B_{12}, and claims 8 and 11 do not require that these two components be present in a "one to one ratio."

The references cited by the Examiner are:

Jurist	2,748,054	May 29, 1956
Sahyun	2,804,423	Aug. 27, 1957

Merck Index, 8th Edition (1968) pages 105, 455, 467-468, 729, 892, 918-919, 1036-1037, 1112-1113.

Physicians' Desk Refeernce (PDR) (1968), pages 738, 915, 1084, 1104, 1129.

Waife et al., *Annals of Internal Medicine*, Vol. 58, No. 5 (May 1963), pages 810-816.

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We add pages 752, 811, and 812 to the Examiner's citation of Physicians' Desk Reference (PDR) because the Peritinic and Zentinic preparations described on those pages correspond generally to the "widely distributed formulation" described on page 5A of appellant's specification. Zentinic is referred to on pages 9 and 10 of appellant's principal brief.

All the claims have been rejected under 35 U.S.C. 101 "as being based on a lack of demonstrated utility that the claimed compositions and methods are safe and effective for the treatment of anemia in humans." This rejection is based on a letter from an official of the Food and Drug Administration to appellant, dated April 1, 1971. Said letter was submitted by appellant as an exhibit attached to his first amendment (Amendment A, Paper No. 3, filed November 8, 1971).

Our decision on the aforementioned rejection is governed by the case of *In re* Anthony, 56 CCPA 1443, 414 F.2d 1383, 162 USPQ 594. As in the cited case, the FDA has not here made an unequivocal finding that the claimed composition is totally unsafe in all circumstances of contemplated use. It is not within our jurisdiction to determine or to enforce the distribution system (over-the-counter or by-prescription-only) or mode of administration of pharmaceutical products. For all that we know, the FDA may ultimately approve prescription distribution of the claimed composition for particular conditions (*e.g.*, vitamin B_{12} deficiency coexisting with folic acid deficiency) with suitable precautions and monitoring after a new drug application with satisfactory proof. These are the functions of the FDA, and *our holding that the claims cannot be rejected under 35 U.S.C. 101 is not to be regarded as approval of all or any particular usage of the claimed composition.* Accordingly, we reverse the rejection under 35 U.S.C. 101.

All the appealed claims have been "rejected under 35 USC 112, second paragraph, as failing to particularly point out and distinctly claim the invention." However, none of the reasons stated by the Examiner are applicable to claims 2 and 9. Accordingly, this rejection must be reversed as to these two claims.

Claims 1, 8, and 11 are held by the Examiner to be indefinite because "at least" fixes no upper limit. We will not sustain the Examiner on this point because appellant's asserted contribution does not reside in determining the upper limits of administration of vitamin B_{12} and folic acid. According to the appealed claims, a therapeutic dose of each of these substances is assured and, in accordance with conventional knowledge in the art, a toxic dose would be avoided.

The Examiner holds claims 3 through 7 to be indefinite because of the parenthetical vitamin designation following the chemical name. He recognizes that the two terms are synonymous and he states that the parenthetical term is redundant. We agree with the appellant that no indefiniteness under 35 U.S.C. 112 results from the parenthetical vitamin identification. Assuming that excessive redundancy is objectionable, yet it appears from the PDR cited by the Examiner that dual identification is commonly employed in the vitamin field.

Claims 5 and 7 are held to be indefinite in the expression "elemental iron." This expression is also found in claim 10. It is quite evident that appellant's composition does not contain "elemental iron" but, rather, iron in the form of a salt (ferrous fumarate). This rejection is not contested by appellant and, inasmuch as it is clearly correct, it will be affirmed.

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Finally, the Examiner holds claim 11 to be indefinite and too broad in "anemia" in the initial portion of the claim and indefinite, functional, and lacking adequate support in the "whereby" clause of the claim. We will not sustain this rejection. The condition for which the claimed method is employed is clear from the language of the claim as a whole. The "whereby" clause of the claim is adequately supported by the last two sentences on page 7 of appellant's specification.

In summation, the rejection under 35 U.S.C. 112 is affirmed as to claims 5, 7, and 10 but is reversed as to claims 1 through 4, 6, 8, 9, and 11.

All the claims have been "rejected under 35 USC 103 as being obvious over Merck in view of PDR, Jurist and Sahyun."

There is no dispute concerning the teachings of the cited references. Appellant recognizes that hematinic vitamin compositions have been prepared and used containing vitamin B_{12} and folic acid, as well as the other vitamins and iron of the more specific claims. Appellant's contribution to the art resides, according to pages 10 and 11 of the principal brief, in providing at least 0.1 mg. (100 mcg.) of each of vitamin B_{12} and folic acid, preferably 0.5 mg. (500 mcg.) of each. No separate argument is presented with respect to the other vitamins and iron of the more limited claims. According to appellant, use of his preparation eliminates the need for differentiating vitamin B_{12} deficiency from folic acid deficiency and the need for administering vitamin B_{12} parenterally and also avoids the dangers of error in diagnosis or masking effect.

Resolution of the issue of obviousness is simplified by appellant's acknowledgment on pages 12 and 13 of his principal brief that folic acid and vitamin B_{12} have been

individually orally administered in dosages of the order here claimed, by reference to FDA regulations and two cited publications. The *Waife et al.* publication, coauthored by appellant, also deals with oral administration of vitamin B_{12} in amounts corresponding to the appealed claims. With this state of the art, the only question which requires answering is whether it would be unobvious to formulate and use a composition containing *both* folic acid and vitamin B_{12} in the recognized therapeutic dosages. Our answer to this question is in the negative, despite appellant's vigorous arguments to the contrary, including his additional citation of a publication after the hearing on this appeal.

As we view appellant's asserted contribution, he has taken a "shotgun" approach to control of anemia, concurrently employing two recognized agents in known amounts for respective deficiencies. We do not use the word "shotgun" as a derogatory adjective, but merely as a convenient descriptive term. We refrain from becoming involved in the medical controversy over the rationality of the shotgun approach. We realize that some condemn the shotgun technique in that it encourages slovenly diagnosis and may result in dangerous "overkill." The contrary argument is that if the shotgun system is not dangerous, no harm is done in administering a broad spectrum of combined therapeutic agents. Our only concern is whether a shotgun composition is obvious rather than whether some practioners would condemn such a composition.

The essence of appellant's position is that because combination therapy is viewed with disfavor by some, it must be unobvious to formulate a combination therapeutic preparation. We cannot agree with appellant's conclusion, despite his emphasis on the premise.

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As for the alleged benefits of appellant's composition, we can perceive nothing unexpected. It is entirely expected that a combination preparation may be used for an undifferentiated disorder. As for oral administration of vitamin B_{12} *vis-á-vis* parental administration, the literature cited in the first full paragraph on page 13 of appellant's principal brief indicates that the effectiveness of oral administration was recognized "as long ago as 1954."

In passing, we find it difficult to distinguish claims 1, 2, and 8 ("at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid") from a double strength tablet of Peritinic (page 752 of PDR) or Zentinic (pages 811 and 812 of PDR), each commercial tablet containing 0.05 milligram of vitamin B_{12} and 0.05 milligram of folic acid, with the recommended dosage being 1 or 2 tablets daily. A double size tablet of Theragran Hematinic (page 1129 or PDR) is also pertinent to claim 8, which does not require a one to one ratio of vitamin B_{12} to folic acid.

In accordance with the foregoing discussion, the rejection of the appealed claims under 35 U.S.C. 103 will be sustained.

The decision of the Examiner is affirmed.

AFFIRMED

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and Naughton
111 Monument Circle
Indianapolis, Indiana 46204

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BOARD OF APPEALS

OCT 30 1974

U. S. PATENT OFFICE

Appeal No. 151-56

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BEFORE THE BOARD OF APPEALS

Ex parte Christian J. Jansen, Jr.

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Before Magil, Schneider and Milestone, Examiners-in-Chief.

Magil, Examiner-in-Chief.

REQUEST FOR RECONSIDERATION AND REHEARING

Appellant requests reconsideration of our decision affirming the Examiner's rejection of claims 1 through 11 under 35 U.S.C. 103. No reconsideration is sought of

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the affirmance of the rejection of claims 5, 7, and 10 under 35 U.S.C. 112.

The request for oral hearing is denied. Our heavy work load precludes oral reargument except under extraordinary circumstances, which are not here present. Appellant's position is well expressed in his written request for reconsideration, which we have carefully studied.

Appellant contends that we have not correctly understood his position and that we have not given adequate consideration to the circumstantial evidence of unobviousness.

We understand appellant's insistence that a composition containing the specified dosages of vitamin B_{12} and folic acid and that the administration of such dosages "eliminate needless sickness and death, and . . . reduce the cost of medical care" (page 2 of Request for Reconsideration), despite adverse criticism and condemnation. However, this running controversy between appellant and "the entire scientific and medical community" (page 4 of Request for Reconsideration) does not serve to establish the unobviousness of the claimed subject matter. As noted in our decision, vitamin B_{12} and folic acid have been included in a single composition and, with respect to dosages, the recommended two-tablet daily dose of Peritinic or Zentinic, corresponds to the terms of claims 1, 2, and 8, with a two-tablet daily dose of Teragran Hematinic also corresponding to the terms of claim 8.

Appellant would have us vindicate his position by holding the appealed subject matter unobvious, thereby proving his critics to be in error. We will not resolve this controversy. Appellant may be correct or his critics may be correct, but the claimed composition and method are clearly obvious from the teachings of the prior art. Our determin-

ation of obviousness is based on a study of the available art, and not on whether one practitioner would apply the label "safe and effective" while another practitioner would apply the label "unsafe and ineffective." We point out that lack of jurisdiction to determine safety and effectiveness led us to reverse the rejection under 35 U.S.C. 101.

We have considered the circumstantial evidence relied on by appellant but, again, this is but part of the picture of the controversy between appellant and those who espouse a contrary view. The condemnation of shotgun therapy does not render such therapy unobvious, the shotgun technique being shown in the art.

Reconsideration has been granted to the extent indicated by the foregoing discussion, but we decline to modify our decision in any respect.

DENIED

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UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

IN THE MATTER OF THE APPLICATION OF CHRISTIAN J. JANSEN, JR.	) Patent Appeal No. 75-556.) Serial No. 57,302.

DECIDED: November 20, 1975

MARKEY, Chief Judge.

This appeal is from a decision of the Patent and Trademark Office Board of Appeals, adhered to on reconsideration, affirming the examiner's rejection of claims 1-4, 6, 8, 9 and 11 in application serial No. 57,302, filed July 22, 1970, for "Hematinic-Vitamin Preparation." We affirm.

The Invention

According to appellant's specification, an inadequate supply of either vitamin B_{12} (cyanocobalamin) or folic acid in the human diet results in fewer healthy red blood cells, producing the symptoms of anemia. Whether the condition is due to vitamin B_{12} deficiency or folic acid deficiency, or to a combination of the two, is difficult, expensive, and time consuming to determine. The determination has been deemed critical. Treatment of a vitamin B_{12} deficient patient with folic acid alone may result in an apparent cure or "masking" of continuing neurological effects of the deficiency and possible irreversible injury or death. Similarly, masking of a folic acid deficiency by administration of vitamin B_{12} alone may result in death, according to appellant's teachings.

Within this context appellant has proposed a solution whereby an oral hematinic multifactor vitamin preparation is administered, the preparation containing both vitamin B_{12} and folic acid, each in the amount of at least .1 milligram. Appealed claims 1 and 11 are illustrative:

> 1. In an improved oral multifactor hematinic vitamin preparation which contains vitamin B_{12} and folic acid, the improvement which comprises having at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid, in an approximate one to one ratio.
>
> 11. A method of treating and preventing anemia in humans which comprises administering a daily oral dosage of a vitamin preparation containing at least .5 mg. of vitamin B_{12} and at least .5 mg. of folic acid, whereby anemia can safely be treated orally without determining whether it is caused by folic acid deficiency or by vitamin B_{12} deficiency.

The Rejection

The references cited by the examiner are as follows:

Jurist	2,748,054	May 29, 1956
Sahyun	2,804,423	Aug. 27, 1957

Merck Index 105, 455, 467-68, 729, 892, 918-19, 1036-37, 1112-13 (8th ed. 1968)

Physicians' Desk Reference (PDR) 738, 915, 1084, 1104, 1129, (1968)

Waife et al., *Oral Vitamin B_{12} without Intrinsic Factor,* 58 *Annals of Internal Med.* 810-16 (1963).

The board added "pages 752, 811, and 812 to the Examiner's citation of Physicians' Desk Reference (PDR)," noting that the Peritinic and Zentinic preparations described therein correspond generally to certain

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"widely distributed formulation[s]" alluded to in appellant's specification.

What the prior art teaches is not in dispute. Appellant has admitted that it is well known to treat a patient having folic acid deficiency with folic acid alone in the amounts claimed. It is also well known to administer folic acid in an oral preparation. The oral administration of vitamin B_{12} alone in the amounts claimed is disclosed in the Waife et al. reference, coauthored by appellant. Oral preaprations containing both vitamin B_{12} and folic acid are also known, although such combination preparations do not contain the amounts claimed by appellant. Zentinic and Peritinic, for instance, are commercially available oral multifactor hematinic vitamin preparations containing .05 milligram of folic acid and .05 milligram of vitamin B_{12}, exactly half the minimum recommended dosage claimed by appellant.

The board had the following comments relative to appellant's asserted contribution, which it referred to as a "shotgun approach" to the control of undifferentiated anemia:

> We refrain from becoming involved in the medical controversy over the rationality of the shotgun approach. We realize that sone condemn the shotgun technique in that it encourages slovenly diagnosis and may result in dangerous "overkill." The contrary argument is that if the shotgun system is not dangerous, no harm is done in administering a broad spectrum of combined therapeutic agents. Our only concern is whether a shotgun composition is obvious rather than whether some practitioners would condemn such a composition.
>
> The essence of appellant's position is that because combination thereapy is viewed with disfavor by some, it must be unobvious to formulate a combination therapeutic preparation. We cannot agree with appellant's conclusion, despite his emphasis on the premise.

The board perceived "nothing unexpected" in appellant's composition, noting that it would be "entirely expected that a combination preparation may be used for an undifferentiated disorder." Moreover, it was determined that appellant's claims, specifying "at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid," were difficult to distinguish from "a double strength tablet" of Zentinic or Peritinic. It was further found that a "double strength tablet" of Theragran Hematinic, which contains .05 milligram of vitamin B_{12} and .5 milligram of folic acid, would be pertinent to claim 8, whcih does not require a one-to-one ratio of vitamin B_{12} to folic acid. On reconsideration the board clarified its position somewhat by commenting:

> As noted in our decision, vitamin B_{12} and folic acid have been included in a single composition and, with respect to dosages, the recommended two-tablet daily dose of Peritinic or Zentinic, corresponds to the terms of claims 1, 2, and 8, with a two-tablet daily dose of Theragran Hematinic also corresponding to the terms of claim 8.

OPINION

We agree with the board that it would have been obvious to formulate and use a composition containing both folic acid and vitamin B_{12} in the recognized individual therapeutic dosages.

Appellant's position is that he has solved the problem of treating anemia in an unobvious way. Appellant relies upon evidence, also considered by the board, tending to show that some or perhaps even most persons having ordinary skill in the art would regard the claimed preparation as unsafe for treating certain types of anemia. A letter from Marvin Seife, M.D., Acting Director, Office of Scien-

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tific Evaluation, Bureau of Drugs, Food and Drug Administration stated:

> Your views on the safety and efficacy of your proposed product are not shared by the preponderance of contemporary scientific medical opinion.

Dr. Seife's letter quoted from a medical textbook:*

> It is therefore incumbent on the physician *never* to prescribe a multi-vitamin preparation containing more than .1 mg. of folic acid per daily dose unless he is reasonably sure that the patient does not have vitamin B_{12} deficiency.

A similar statement, apparently reflecting the opinion of the American Medical Association, is expressed in *AMA Drug Evaluations* 61 (1st ed. 1971):

> Combination therapy is indicated only when it can be clearly demonstrated that one type of anemia is superimposed upon another. Even under these circumstances, a combination of *the specific agents lacking in the particular anemias diagnosed are the only agents that should be used to treat the anemias.* Not only is avoidance of mixtures superior therapy from the standpoint of good medical practice, but also it may be absolutely necessary because the preferred route of administration of two different therapeutic agents may be entirely different. For example, an iron deficiency anemia superimposed on a pernicious anemia requires both iron and cyanocobalamin for treatment. However, the oral route is preferred for administering iron, whereas cyanocobalamin should be given by intramuscular or deep subcutaneous injection for best results.

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* Goodman & Gilman, *The Pharmacological Basis of Therapeutics*, 1440 (4th ed. 1970).

Appellant raises an unnecessary issue in arguing that the board has jurisdiction to consider opinions of the Food and Drug Administration and others concerning the safety and effectiveness of the claimed composition insofar as such opinions may relate to the question of obviousness under section 103, citing *In re Anthony*, 56 CCPA 1443, 414 F.2d 1383, 162 USPQ 594 (1969). The board properly cited *In re Anthony* as authority for its reversal of a rejection under 35 USC 101 and thereafter proceeded, in its review of the rejection under 35 USC 103, to consider fully the opinion evidence respecting safety submitted by appellant. Nothing in *In re Anthony* militates against jurisdiction of the board to consider such evidence in relation to the question of obviousness. The board determined, however, that such evidence was not persuasive of unobviousness in the claimed subject matter. We agree with that determination.

Whether members of the medical community agree or disagree with appellant's "shotgun approach" to treating undifferentiated anemia cannot control the determination of whether appellant's claimed combination product and method would have been unobvious to a person having ordinary skill in the art. The prior art is replete with examples of commercially available hematinic vitamin preparations containing combinations of vitamin B_{12} and folic acid. Hence, there is nothing new or unobvious in the combination per se. Neither is there anything new or unobvious about the individual dosage levels for vitamin B_{12} and folic acid employed by appellant.

Appellant asserts a theory concerning the manner in which the claimed composition and method effectively treat undifferentiated anemia. We express no view on the merit of that theory. Appellant's theory, however, cannot remove the effect of the prior art, which establishes that the

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claimed composition and method would have been obvious to one of ordinary skill in the art.

Accordingly, the decision of the Patent and Trademark Office is *affirmed.*

AFFIRMED

PA 75-556